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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,876	06/25/2003	Paul Goode	13569.0012US01	3012
23552	7590	09/22/2005	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			FAULCON JR, LENWOOD	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/603,876	GOODE, PAUL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Lenwood Faulcon, Jr.	3762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 June 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/24/03 &amp; 12/13/04</u>   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 as written is dependent on claim 7 and thus is rejected as indefinite.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 8-16, 18, 24, 26, 28-29, 31, 35-36, 38-39, 41-45 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Levine et al. (U.S. Patent No. 6,058,328).

Levine et al. teaches of an implantable stimulation device having the ability to provide preemptive tachyarrhythmia pacing by predicting the occurrence of a tachyarrhythmia (col. 2 lines 56-59 and col. 3 lines 4-10). Levine et al. teaches of forming a template of a patient's heart normal behavior and monitoring for abrupt changes from the template may trigger the preemptive tachyarrhythmia pacing

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algorithm (col. 5 lines 5-16). Levine et al. also teaches that a trigger for the preemptive action of the system may be the monitoring of one or more sensed physiological-based parameters of the patient, such as intra-chamber impedance of the heart, pre-ejection interval or stroke volume (col. 5 lines 17-26).

Levine et al. teaches developing an algorithm that recognizes parameters indicative of a patient being at different physical activity levels, including rest or involved when the patient is exercising (col. 29 lines 44-48 Levine et al. further teaches of the use endocardial electrodes for sensing arrhythmia (col. 7 lines 27-31). Levine et al. also teaches of the use of an external programmer that has the ability to receive data from the implantable device (col. 10 lines 58-67).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 5-7, 17, 19, 25, 27, 30, 32-34, 37, 40, 46 and 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (U.S. Patent No. 6,058,328) as applied to claims 1-4, 8-18, 24, 26, 28-29, 31, 35-36, 38-39, 41-45 and 47 above.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught Levine et al. to include parameters for when a patient is at rest and not at rest, since these parameters are well known in the art and are commonly derived for use with cardiac monitoring devices. It would have

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also been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Levine et al. to use a measured voltage between two electrodes to calculate an impedance, since this type of measurement and calculation is well known in the art to provide an impedance value.

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Levine et al. to have the derived physiologic cardiac parameter correlate to sympathetic and parasympathetic activity as they are commonly known in the art to be contributing factors to the rate of spontaneous discharge which directly relates to the initiation of a pathologic tachyarrhythmia, as taught by Levine et al. (col. 34 lines 50-61).

7. Claims 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (U.S. Patent No. 6,058,328) as applied to claims 1-4, 8-18, 24, 26, 28-29, 31, 35-36, 38-39, 41-45 and 47 above, and further in view of Koestner et al. (U.S. Patent No. 5,300,093).

Koestner et al. teaches of an apparatus and method for measuring, formatting and transmitting combine intracardiac impedance data and electrograms, comprising the use of unipolar and bipolar measurement modes (col. 11 lines 34-55).

It would have been obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Levine et al. and the teachings of Koestner et al. Levine et al. and Koestner et al. both teach of programmable implanted cardiac stimulation devices that measure intracardiac impedance and thus teach of analogous arts. It would have obvious to one having ordinary skill in the art at the time of the

invention to modify the systems as taught by Levine et al. to have the electrodes in various configurations such as those taught by Koestner et al. since these configuration are well known in the art to provide efficient and accurate sensing.

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Langer et al. (U.S. Patent No. 4,202,340), Geddes et al. (U.S. Patent No. 5,058,583), Nappholz et al. (U.S. Patent No. 5,113,869), Chirife (U.S. Patent No. 5,154,171), Sackner (U.S. Patent No. 5,178,151), Street et al. (U.S. Patent No. 6,589,188), Meyer (U.S. 2001/0003160), Geeske et al. (EP 0985429 A2), Schaldach ("Automatic Adjustment of Pacing Parameters Based on Intracardiac Impedance Measurements," Pacing and Clinical Electrophysiology, 1990, pgs 1702-1710.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lenwood Faulcon, Jr. whose telephone number is 571-272-6090. The examiner can normally be reached on Monday-Thursday from 9 to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



Lenwood Faulcon, Jr.



George Manuel

Primary Examiner